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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,971	07/30/2001	Khalid Mentak	088261-9138-003	1604

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MICHAEL BEST & FRIEDRICH, LLP
ONE SOUTH PINCKNEY STREET
P O BOX 1806
MADISON, WI 53701

EXAMINER

ZALUKAEVA, TATYANA

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/917,971

Applicant(s)

MENTAK, KHALID

Examiner

Tatyana Zalukaeva

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 33, 34 and 37 stand rejected under 35 U.S.C. 102(b) as being anticipated by Stoy (U.S. 4,731,079), as per reasons of record.

Stoy discloses a method of making an intraocular lens (IOL), the embodiment presented in Example 2 clearly reads on the limitations of the instant claims 33, 34 and 37. Thus, 85 grams of benzyl Acrylate, (first monomer of the instant claim 33) 15 grams of styrene (second monomer of the instant claim 33) and 0.35 grams of tetraethyleneglycol-bis-methacrylate (third monomer of the instant claim 33) were polymerized under nitrogen by means of 0.075 grams of benzoylperoxide. Refractive index was 1.570. Ts (Tg) is 25.5°C.

The copolymer was lathed into the shape of a biconvex lens.

The lens was then inserted in a tube made from a roll of stainless steel, 0.5 mm in thickness. The roll and the lens were immersed in nearly boiling water for several seconds. Then the roll containing the deformed lens was immersed in a jar of saline. (this is a hydrating step) The deformed (or foldable) lens was readily insertable through a facoemulsification incision by means of forceps or another suitable instrument. (see Example II in columns 14 and 15). This meets the limitations of the instant claims 33 and 37. According to Stoy, when the finished lens is placed in an isotonic saline solution for 24 hours at ambient temperature, from the lens' weight

increase it was found that its equilibrium water content was about 10% by weight. (column 16, lines 10-15).

3. Claim 35 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stoy.

The property of central thickness is not elucidated by Stoy. However, there are two aspects Examiner would like to address here. The first one is that since the polymers of Stoy are essentially the same as instantly claimed, and they are made via essentially the same method as instantly claimed, therefore the properties even not taught, will be inherently the same as a per In re Fitzgerald (205 USPQ 594). (CAFC) The onus to show that this, in fact, is not the case is shifted to applicants

The second consideration is that Stoy teaches that at 31.5 Diopters the central thickness is 0.73 mm. If the proportion works in this case (taking into account the identity of the claimed and disclosed products) than the thickness at 20 Diopters should be close the claimed range $(20 \times 0.73 / 31.5) = 0.46$.

4. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stoy. Stoy does not specify the sequence of hydrating steps.

However, Stoy clearly suggest plasticizing with water or saline solution, and suggests different modes of such plastification. Considering the absence of criticality of the particular mode of hydration, and the generic teaching of Stoy with regard to hydration, a person skilled in the art would have found it obvious to utilize any mode including one of the instant claims with the reasonable expectation of success. In re

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Burhans 69 USPQ 330 (CCPA 1946): Selection of any order of performing process steps is prima facie obvious in the absence of new and unexpected results

Response to Arguments

5. Applicant's arguments filed February 19, 2003 have been fully considered but they are not persuasive. Applicants arguments reside in contention:

- a) The Ts of Stoy is not necessarily identical to Tg, as recited in the instant claims;
- b) The tetraethylene glycol –bis-methacrylate is not a hydrogel forming monomer of the instant claims, but rather a crosslinking monomer;
- c) Although Stoy discussed the need for hydration, only the surface hydration is described.

In response to this Examiner will address each issue individually:

a) first of all Stoy expressly teaches that Ts may correspond to glass transition temperature, which has a well known and well defined meaning (col. 6, lines 54, 55). This teaching is already sufficient for anticipation of Tg by Stoy. However, if *arguendo* the Ts of Stoy does not have the same meaning as Tg, the Tg of Stoy would still be inherently the same as that of instantly claimed copolymers, because products of identical chemical composition cannot have mutually exclusive properties. Therefore if the prior art teaches the identical chemical structure, the properties and characteristics applicant discloses and/or claims are necessarily present. **In re Spada**, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990);

b) first of all Applicants do not name the high water content hydrogel forming comonomer in either one of the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the references cited in PTOL-892, submitted along with this Office Action show that tetraethylene glycol –bis-methacrylate is a hydrogel forming high water content monomer. (U.S. 5,453,530, see col. 9, lines 32-40; U.S. 4,962,170, see col. 3, lines 44-46). It is noted that the cited references **are in no way used for new grounds of rejection, but to rebut Applicants' arguments with documentary evidence.**

c) with regard to the "surface hydration" of Stoy versus "hydration of the instant claims", it is noted that "type of hydration" is not recited in the instant claims. Therefore, Applicants arguments are more specific than the claims.

Applicants arguments on the obviousness rejection are based on presumption that the anticipation rejection of base claims is withdrawn, which is not presently the case.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

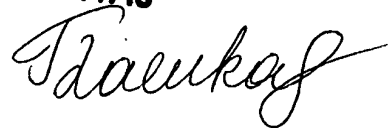
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tatyana Zalukaeva whose telephone number is (703) 308-8819. The examiner can normally be reached on 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (703) 308-2450. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0651.

Tatyana Zalukaeva, Ph.D.
Primary Examiner
Art Unit 1713



May 20, 2003